

Section II. Amendments to the Specification

Please add and/or amend the following paragraphs of the specification as set forth below.

[0016A] Figure 6 illustrates a perspective view of a kit comprising a delivery assembly according to the present invention disposed within a package having instructions or indicia disposed on the packaging material.

[0027] In an embodiment, at least part of the system 100 may be incorporated as a kit 600 such as illustrated in FIG. 6. For example, the kit 600 may include the first delivery assembly 140 along with packaging material 601 and instructions or indicia 602 located on the packaging material 601 or inside the packaging material 601. In one such embodiment, the substance 104 is included in such a kit 600.

Section III. Remarks

Claims 1, 2, 5, 9, 12, 13, 19, 20, 27, 31, 32, 36-38, 44, and 47 have been amended herewith (including renumbering of claims 9, 19, 20, 27, 36-38, 44 and 47), and 8, 10, 11, 14-18, 21-26, 28-30, 33-35, 39-43, 45, and 46 have been renumbered. No new matter has been added pursuant to 35 U.S.C. § 132. Claims 1-47 are currently pending in the application.

A. Allowable Subject Matter

Claims 3, 4, 7, 8, 16, 18, 21, 35, 36, 39, 46, and 47 were objected to as being dependent on a rejected base claim, but were indicated to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The Examiner indicated as patentable subject matter of claims 4, 7, 16, 35 and 46 the feature of “a slit or cut that does not penetrate completely through the membrane” in combination with other claimed elements.

The Examiner indicated as patentable subject matter of claims 3, 18, 36 and 47 the feature of “a latch coupled between the container and the hollow connector” in combination with other claimed elements.

The Examiner indicated as patentable subject matter of claims 21 and 39 the feature of “a connector being configured to attach to the container via a threaded connection” in combination with other claimed elements.

Based on the amendments and arguments provided herein, all of the base claims on which 3, 4, 7, 8, 16, 18, 21, 35, 36, 39, 46, and 47 depend are allowable in their current form. Thus, allowance of all of these claims is respectfully requested.

B. Objections

1. Objections to the Numbering of the Claims

The originally filed claims were numbered 1-49 but due to typographical error, reference to claim numbers 8 and 9 was omitted from the application, and claims 8-9 never existed in the application. Originally filed/misnumbered claims 10-49 have been renumbered 8-47, with the

dependency of various claims also corrected accordingly. Applicant does not consider amendments solely to renumber the claims (i.e., to correct typographical errors), to be related to patentability.

2. Objection to the Drawings as Relating to Claims 46-49

The drawings were objected to under 37 CFR 1.83(a); specifically, the kit as claimed in original claims 46-49 (renumbered as claimed 44-47) was required to be shown in the drawings or the feature(s) cancelled from the claims. New drawing sheet 5 (including Figure 6) is provided herewith to clearly show the kit as claimed in claims 44-47. Support for new drawing sheet 5 is provided in the original application text, for example, at paragraph number [0027]. No new matter has been added.

C. Claim Rejections

1. Rejections Under 35 USC § 112

Claim 10 as originally presented (now claim 8) was rejected under 35 USC § 112, second paragraph, as being indefinite for being dependent on non-existent claim 9. The claim is now properly re-numbered as claim 8, and the dependency of claim 8 has been corrected to depend from claim 7. Withdrawal of the rejection under 35 USC § 112 is respectfully requested.

Claim 1 was rejected for lacking antecedent basis for the limitation “transferring the fluids” in line 6. Claim 1 has been amended herewith to properly introduce “at least one fluid” before claiming the transfer of “the at least one fluid.” Withdrawal of the rejection under 35 USC § 112 is respectfully requested.

2. Rejections Under 35 USC § 102

Claims 1, 2, 5, 9-11, 17, 19, 20, 22-30, 37, 38, and 40-43 were rejected under 35 USC § 102 as anticipated by U.S. Reexamination No. 25,129 to Walter (hereinafter “Walter”). Independent claims 1, 5, 9, and 27 have been amended herewith. Applicant respectfully traverses these rejections.

a. Disclosure of Walter

Walter discloses an apparatus having multiple containers for holding a medical fluid such as blood, and then dispensing the fluid from the containers. For example, blood drawn by needle

from a donor's arm flows by gravity through tubing into an ion exchange column and then into a bag 10 for storage. Walter, col. 6, lines 38-74. The bag 10 is fashioned from a thin flexible wall enabling the bag "to be completely collapsed flatwise before filling, ridding it of air and precluding any appreciable liquid-gas interface." Id., col. 3, lines 27-30 (emphasis added). After filling, the bag 10 is sealed for storage. Id., col. 6, lines 56-75.

The bag 10 has an inlet tube 13 and a delivery tube 16 disposed at an outlet. Id., col. 3, lines 53-73. Two separate seals are initially associated with the delivery tube 16: a first inner seal comprising "a piercable diaphragm of about 1 mm thickness ... at the inner end of the tube, as indicated at 16a" (col. 4, lines 1-4) and "[a] protective tubular sheath 17 ... [enclosing] the protruding portion of the delivery tube" Id., col. 4, lines 1-12. This sheath affords a second and outer seal for the delivery tube [16] so that the bag [10] is subject to a double seal at this location." Id., col. 4, lines 12-14.

A coupling needle is necessary to administer the contents of the bag, as follows:

"[T]he end of the protective sheath 17 is cut away from the delivery tube 16 at the bottom of the bag [10]. The **coupling needle 47** is then withdrawn from the sheathing tube 52 and is **inserted into and through the delivery tube 16** so as to **pierce the inner sealing diaphragm 16a** thereof and provide a passage for the blood."

Walter, col., 7, lines 3-32 (emphasis added). Thereafter, blood is delivered through the hollow coupling needle 47, a tube 40, and an infusing needle to enter the recipient. Id.

b. Law Regarding Anticipation

"Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration." *W.L. Gore & Assocs. v. Garlock*, 721, F.2d 1540, 220 USPQ 303 at 313 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). It is not enough that the prior art reference disclose all the claimed elements in isolation. Rather, "anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim." *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (emphasis added). Further, "[u]nder 35 U.S.C. § 102, anticipation requires that ... the prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public." *Akzo, N.V. v. United States Int'l Trade Comm'n*, 808 F.2d 1471, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986).

c. Walter Does Not Disclose The Subject Matter of Independent Claims 1 & 5

Independent claims 1 and 5 require the presence of a pressurized gas (e.g., pressurized to greater than 1 atmosphere) bounded by a membrane enclosing a hollow connector having a piercing element. When the seal is broken by the piercing element to provide a fluid transfer interface between containers, outward flow of the pressurized gas prevents ingress of environmental contaminants into the interface. As mentioned in the summary of the invention of the present application, providing a flow of gas during connection of a first container to a second container provides the advantage of “preclud[ing] the infiltration of contaminants from the ambient environment.” (Description, ¶0005.)

Walter fails to disclose the presence of any pressurized gas bounded by a membrane enclosing a hollow connector and adapted to generate a laminar outward flow upon puncture. The possibility that some air may be present within the sheath 17 (see Office Action, page 4) does not compel the conclusion that such air has a greater than atmospheric pressure (e.g., at the time of puncture), or that it generates a laminar flow of gas upon puncture of the membrane, such as required by claims 1 and 5. Walter expressly provides that the “end of the protective sheath 17 is [first] cut away from the delivery tube 16,” thus exposing the inner sealing diaphragm 16a for subsequent puncture. Walter, col., 7, lines 3-32. Moreover, the inner sealing diaphragm 16a bounds the bag 10, which is “completely collapsed flatwise before filling, ridding it of air and precluding any appreciable liquid-gas interface.” Walter, col. 3, lines 27-30.

Claims 1 and 5 also require that the “piercing element of the connector” be used to pierce an opening in the membrane housing. Walter contains no such teaching. Rather, Walter teaches that “the end of the protective sheath 17 is [first] cut away from the delivery tube 16” and then a separate “coupling needle 47” is inserted into and through the delivery tube 16 to pierce the inner sealing diaphragm 16a and provide a fluid passage.” (Emphasis added).

Since “anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim,” (*Lindemann, supra*), and Walter fails to teach each and every element of the claimed invention, Walter cannot support the

above-mentioned rejections under 35 USC § 102. Withdrawal of these rejections is respectfully requested.

d. Walter Does Not Disclose The Subject Matter of Independent Claims 9, 27, and 44

Amended independent claims 9, 27, and 44 all require the presence of at least one of:

- (i) gas having a pressure of greater than about 1 atm inside the chamber;
- (ii) a partial slit or cut in the interior surface of the membrane that does not penetrate completely through the membrane;
- (iii) a latch coupled between the container and the hollow connector; and
- (iv) the hollow connector is configured to engage the container via a threaded connection.

As noted above in section III.A, the Examiner has already indicated features (ii) through (iv) to be directed to patentable subject matter, thus focusing any need for discussion solely on feature (i), namely, the gas having a pressure of greater than about 1 atmosphere inside the chamber.

The failure of Walter to teach or suggest a gas having a pressure of greater than about 1 atmosphere inside a chamber has already been established hereinabove. The Examiner's conjecture that air may be present within the sheath 17 (see Office Action, page 4) is not a sufficient basis to support an anticipation rejection.

"Inherency, however, may be not be established by probabilities or possibilities. The mere fact that a certain thing may results from a given set of circumstances is not sufficient."

In re Oelrich, 666 F.2d 578, 581, 212 USPQ2d 323, 326 (CCPA 1981)

Even if air were present in the sheath, there is no basis in Walter for the Examiner's speculation that such air is pressurized. On these facts, the anticipation rejection under 35 USC 102 must fail, and withdrawal of the rejection is respectfully requested.

Remaining claims 2, 10, 11, 17, 19, 20, 22-26, 28-30, 37, 38, and 40-43 all depend from claims 1, 5, 9, and/or 27. Since dependent claims incorporate all of the limitations of the claims on which

they depend and thus constitute subsets of such claims, withdrawal of the rejections under 35 USC §102 of dependent claims 2, 10, 11, 17, 19, 20, 22-26, 28-30, 37, 38, and 40-43 is also requested.

3. Rejections Under 35 USC § 103

Claims 6, 12-15, 31-34, 44, and 45 were rejected under 35 USC § 103 as being unpatentable over U.S. Reexamination No. 25,129 to Walter (“Walter”). Applicant respectfully traverses these rejections.

Claims 6, 12-15, 31-34, 44 and 45 all require the presence of a pressurized gas bounded by a membrane enclosing a hollow connector. Walter fails to teach or suggest this feature, as discussed in detail above. The Examiner opined that “[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to choose a pressure for the air/gas within the sheath to be greater than about 1.05 atm.” Such a conclusion does not flow from Walter, particularly since Walter teaches *the expulsion of air* from a container (col. 3, lines 27-30) – thus teaching away from providing pressurized air proximate to a connector. For at least this reason, claims 6, 12-15, 31-34, 44 and 45 are non-obvious over the disclosure of Walter and the rejections under 35 USC § 103 should be withdrawn.

C. Allowable Subject Matter

Claims 3, 4, 7, 8, 16, 18, 21, 35, 36, 39, 46, and 47 were objected to as being dependent on a rejected base claim, but were indicated to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Based on the foregoing amendments and arguments, all of the base claims on which 3, 4, 7, 8, 16, 18, 21, 35, 36, 39, 46, and 47 depend are allowable in their current form.

D. Conclusion

Claims 1-47 as provided herein and now pending in the application are in form and condition for allowance. Issuance of a Notice of Allowance for the application is therefore requested. If any issues remain outstanding, incident to the formal allowance of the application, the Examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss same, in order that this application may be allowed and passed to issue at an early date.

Respectfully submitted,



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Enclosures: New drawing sheet 5
Power of Attorney (Form PTO/SB/80)
Statement Under 37 C.F.R. 3.73(b) (form PTO/SB/96)